DEC 2 6 2013

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Direct: (262) 347-1250
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k133422

NeoCoil

5. Abbreviated 510(k) Summary

5.1. Applicant
NeoCoil, LLC
N27 W23910A Paul Rd
Pewaukee, WI 53072 USA

5.2. Contact
Katie Gonzalez
Engineering Services Specialist
262-522-6124 (direct)
261-347-1251 (fax)
Katie.Gonzalez@NeoCoil.com

5.3. Preparation Date
11/07/2013

5.4. Name of Device
- Proprietary Name: 1.5T 16-Channel Flex Coils
- Common Name: Magnetic Resonance Specialty Coil
- Classification: 21 CFR 892.1000, Product Code MOS

5.5. Model Numbers

NeoCoil Model Number	NeoCoil Model Name
NC052000	1.5T 16-Channel Flex Coil, Small
NC053000	1.5T 16-Channel Flex Coil, Large

5.6. Device Description
The NeoCoil 1.5T 16-Channel Flex Coils for Siemens is a system of phased array, receive-only coils. The system consists of:
- Two formable, flexible and detachable antennae of different size that can be wrapped or orientated flat, in order to accommodate various anatomic shapes and sizes.
- Optional accessories designed for patient comfort and reduced motion artifacts.

The NeoCoil 1.5T 16-Channel Flex Coils for Siemens are tuned to receive RF frequency corresponding to the proton precession in a 1.5 tesla magnetic field, which is governed by the Larmor equation.

5.7. Predicate Device
- 1.5T 16ch Flex SPEEDER Coil (K121362), cleared on 06/15/2012

5.8. Comparison to Predicate
The NeoCoil 1.5T 16-Channel Flex Coils for Siemens are similar in physical, performance, design and material characteristics to the legally marketed device, the 1.5T 16ch Flex SPEEDER, K121362, as cleared on 06/15/2012.

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The differences introduced in this submission include:

- Electrical interface modifications to meet the Siemens MAGNETOM Coil Interface Description.
- Cable and connector material modifications to utilize Siemens specified materials. All materials have been evaluated for biocompatibility.
- Minor dimensional changes compared to the 1.5T 16ch Flex SPEEDER, resulting from the plastic housing modifications to accommodate electrical interface changes.

The Indications for Use are consistent with the capabilities of the predicate device, the NeoCoil 1.5T 16ch Flex SPEEDER Coil, K121362 as cleared on 06/15/2012.

Clinical testing demonstrates that the differences in the devices do not affect the safety and/or the effectiveness of the device when used as labeled.

5.9. Indications for Use

To be used in conjunction with Siemens 1.5T MAGNETOM MRI scanners to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis and spine that can be interpreted by a trained physician.

5.10. Intended Use

Intended use of the NeoCoil 1.5T 16-Channel Flex Coils for Siemens is identical to that of routine MR imaging; specifically to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis and spine.

Use of the device in conjunction with an MRI scanner is unchanged.

5.11. Testing

The following data has been submitted, referenced or relied on to demonstrate that the NeoCoil 1.5T 16-Channel Flex Coils for Siemens are safe and effective. The devices' performance meets the requirements of pre-defined acceptance criteria and intended uses.

Performance testing - Bench:

Test	Pass/Fail Criteria	Result
Unplugged Surface Temperature	Acceptable level of risk	**Pass:** Surface temperature is not greater than 41°C when the coil is left unplugged in the MRI scanner.
Surface Temperature	Pre-defined performance standards	**Pass:** RF and Eddy current heating is not greater than 41°C.
Blocking Network Analysis	Adequate transmit decoupling	**Pass:** Blocking network demonstrates adequate active and passive transmit decoupling.
B1 Field Distortion	Pre-defined performance standards	**Pass:** B1 field inhomogeneity meets Siemens performance requirements and demonstrates adequate active and passive transmit decoupling.
NEMA MS 6-2008	Pre-defined performance standards	**Pass:** SNR and Image Uniformity are consistent with the requirements for indications for use.

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Published Standards testing:

Standard	Purpose
IEC 60601-1	Electromechanical safety
IEC 60601-1-2	ESD
IEC 60601-2-33	Electromechanical safety
ISO 10993-1	Biocompatibility
NEMA MS-6	SNR and Image Uniformity

Performance testing - Clinical:

Clinical data submitted exhibits a mix of scanner configurations, pulse sequences, imaging options, field of view and anatomy in the axial, sagittal and coronal planes as recommended in the FDA guidance, *Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices.*

No adverse events were reported during clinical performance testing; the 1.5T 16-Channel Flex Coil, Large and 1.5T 16-Channel Flex Coil, Small demonstrated performance adequate to support the Indications for Use.

5.12. Conclusion

This submission demonstrates that the Indications for Use are in line with the predicate device to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis and spine and are as safe and effective as the predicate device. As such, NeoCoil 1.5T 16-Channel Flex Coils for Siemens are equivalent to their predicate, 1.5T 16ch Flex SPEEDER Coil, K121362 as cleared on 06/15/2012.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 26, 2013

NeoCoil, LLC
% Ms. Katie Gonzalez
Engineering Services Specialist
N27 W23910A Paul Road
PEWAUKEE WI 53072

Re: K133422
Trade/Device Name: 1.5T 16-Channel Flex Coil, (Small-NC052000 and Large-NC05300)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 7, 2013
Received: November 8, 2013

Dear Ms. Gonzalez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k133422

Device Name: 1.5T 16-Channel Flex Coils

Indications for Use:

To be used in conjunction with Siemens 1.5T MAGNETOM MRI scanners to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis and spine that can be interpreted by a trained physician.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K133422